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EXAMINER

YABUT, DIANE D

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### DETAILED ACTION

This action is in response to applicant's amendment received on 05/15/2009.

#### *Information Disclosure Statement*

1. The information disclosure statement (IDS) submitted on 03/24/2009 is considered. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 45-46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBroom et al., hereinafter "**McBroom**" (U.S. Patent No. **6,277,108**).

McBroom discloses a sheath body **140**, the sheath body having a distal end and including a longitudinally extending sheath score line ("weakened portion") running along a length of the sheath body, and a tearable, contiguous radiopaque ring **160**, **330**, **500** or **700** abutting a distal end of said sheath body, the radiopaque ring defining gaps or score lines ("perforated lines") **512** running along the radiopaque ring and separating several marker segments which may be broken by tearing and may be aligned with said sheath score line ("as the sheath **140** is severed, the marker band **160** is also severed").

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The radiopaque ring score line may be located or bonded to an inner wall of the sheath body. See abstract, Figures 1, 4, 6, 9; col. 1, lines 38-41, col. 3, line 54 to col. 4, line 67, and col. 5, lines 3-34.

McBroom does not expressly disclose first and second marker segments being discrete, or separate and not connected to one another. However, McBroom teaches several radiopaque marker segments including several gaps **512** in Figure 6 which may separate the radiopaque marker into discrete segments by using slots, such as vertical slot **712**. It would occur to one of ordinary skill in the art to have two discrete marker segments in order to further facilitate splitting the combined sheath and radiopaque marker simultaneously, and therefore make them easily removable from a medical device (col. 6, lines 2-12). It is also noted that applicant has disclosed in paragraph 8 of the specification that the discrete portions of the radiopaque marker “may or may not be in direct contact with one another.” Therefore, modifying the radiopaque marker segments of McBroom to be discrete would have occurred to one skilled in the art since applicant has not disclosed that having the segments be discrete solves any stated problem or is for any particular purpose and it appears that the radiopaque marker would perform equally well with the segments being discrete.

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4. Claims 47 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over **McBroom** (U.S. Patent No. **6,277,108**) in view of **Dehdashtian et al.** (U.S. Patent No. **5,968,068**).

McBroom discloses the claimed device except for the radiopaque marker being embedded within the sheath body, or the distal end of the sheath body being separated into an inner ring and an outer ring via a longitudinal cut around its perimeter with the radiopaque ring sealed between the inner and outer rings.

Dehdashtian et al. teach a radiopaque marker **32** being embedded within a sheath body **23**, or the distal end of the sheath body being separated into an inner ring and an outer ring via a longitudinal cut around its perimeter with the radiopaque ring sealed between the inner and outer rings (Figure 8). It would have been obvious to one of ordinary skill in the art at the time of invention to embed the radiopaque marker of McBroom in the sheath body, as taught by Dehdashtian et al., to provide a smooth, non-traumatic outer surface of the sheath while still allowing the marker to be readily and apparently visible (col. 26, lines 30-36).

5. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over **McBroom** (U.S. Patent No. **6,277,108**) in view of **Norlander et al.** (U.S. Patent No. **6,562,049**).

McBroom discloses the claimed device, except for a second sheath score line running substantially along said length of the exterior surface of said sheath body,

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located approximately opposite the first sheath score line, which would align with the second marker score line or notch.

Norlander et al. teach first and second sheath score lines **46** running substantially along a length of a sheath body **11** and located approximately opposite one another along an interior of said sheath body (Figures 6-8; col. 6, lines 50 to col. 7, line 14). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a second sheath score line, as taught by Norlander et al., to McBroom since it was known in the art that multiple score lines facilitate removal of the sheath in that it can be split more efficiently when positioned at different orientations or when one score line is not easily accessible on the opposite side. Since McBroom anticipates multiple radiopaque marker score lines **512** it would occur to one of ordinary skill to align multiple sheath score lines to these to further facilitate splitting.

6. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over **McBroom** (U.S. Patent No. **6,277,108**) in view of **Norlander et al.** (U.S. Patent No. **6,562,049**) and **Dorn et al.** (U.S. Pub. No. **2002/0183826**).

McBroom and Norlander et al. disclose the claimed device (see paragraphs above) except for the inner surface of the tubular body of the radiopaque marker ring being formed in a funnel shape at a proximal end thereof.

Dorn et al. teach an inner surface of a tubular body of a radiopaque marker **226** ring being formed in a funnel shape at a proximal end thereof (Figure 5, paragraph 89). It would have been obvious to one of ordinary skill in the art at the time of invention to

provide a funnel shape to the radiopaque marker of McBroom, as taught by Dorn et al., in order to conform to a tapered tip of the sheath or to facilitate insertion into the body.

### ***Response to Arguments***

7. Applicant's arguments filed 05/15/2009 have been fully considered but they are not persuasive.

8. Applicant generally argues that examiner's conclusion of obviousness is based upon improper hindsight reasoning. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. As maintained above, it would occur to one of ordinary skill in the art to modify McBroom by having two discrete marker segments in order to further facilitate splitting the combined sheath and radiopaque marker simultaneously, and therefore make them easily removable from a medical device (col. 6, lines 2-12). The applicant's teaching disclosed in paragraph 8 of the specification that the discrete portions of the radiopaque marker "may or may not be in direct contact with one another," is not used to show obviousness, but rather to show that that the radiopaque marker of McBroom would perform equally well with the segments being discrete since no purpose or problem is being addressed by the discrete marker portions. Also, making the "unitary marker" of McBroom into discrete first and second marker segments would be obvious to one of

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ordinary skill in the art, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

9. Next, applicant argues that Dehdashtian does not teach a longitudinal cut that separates the distal end of the sheath body into an inner ring and an outer ring, but instead embedding a radiopaque marker by removing material from the sheath and then placing the marker within the sheath. The examiner asserts that the space created by removing material from the sheath may be considered to be a “longitudinal cut.” The motivation of providing a smooth outer surface of the sheath, the applicant argues, does not exist since McBroom teaches disposing a marker on the inner surface of the sheath, already leaving the outer surface smooth. However, this is only one embodiment, and there are several others manners in McBroom for disposing the marker on the sheath (col. 4, lines 59-67).

10. Lastly, applicant argues that Dorn does not teach or suggest an inner surface of a tubular body of a radiopaque marker ring being formed in a funnel shape at a proximal end thereof, but rather just the tip of a catheter system. Dorn teaches a “radiopaque tip” **226** (paragraph 89), which is a tubular body and acts as a radiopaque marker, and therefore reads on this limitation.



***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734